

## **DEPARTMENT OF FOOD AND AGRICULTURE**

### **INITIAL STATEMENT OF REASONS**

**Hearing Date:** No public hearing is scheduled for this proposal. A public hearing will be held if any interested person, or his or her duly authorized representative, submits a written request for a public hearing to the Department of Food and Agriculture no later than 15 days prior to the close of the written comment period.

**Subject Matter of Proposed Regulations:** Personal Licenses; Fluid Milk  
Composition Testing Methods

**Section(s) Affected:** Various Sections of Articles 13, 14, 14.5, 14.6, 14.7, 14.8 and 21.

#### **Specific Purpose of Each Adoption, Amendment, or Repeal**

Existing Law, Food and Agricultural Code sections 32921, 34261.5, 35161, 35162, 35163, 35164, 35166, 35167, 35168, 35169, 35170, 35171, 35784, 35231, 38181, 38191 and 39211 set forth the requirements for the application, examination and licensure for a pasteurizer's license, tester's license, sampler's and weigher's license, technician's license, and the requirements to test fluid milk composition.

To implement the above-referenced statutes, the Department of Food and Agriculture (Department) has in place regulations under Articles 13, 14, 14.5, 14.6, 14.7, 14.8 and 21 of Chapter 1, Division 2, Title 3, of the California Code of Regulations.

This proposal updates these regulations to clarify the application forms and requirements for persons applying for examination and licensure for processing milk or milk products in California. This proposal also updates the fluid milk compositional testing standards initiated (in part) by a petition received from the Dairy Institute of California dated October 24, 2002. This proposal also makes nonsubstantive wording and grammatical changes for clarity purposes.

#### **Factual Basis**

California is the leading milk producing state in the nation producing nearly 35 billion pounds of milk in 2002. California currently produces over 20% of the nation's milk and dairy products supply. The Department's Milk and Dairy Food Safety Branch is charged with the mission and responsibility of ensuring that California's milk, milk products, and products resembling milk products are safe and wholesome, and meet microbiological and compositional requirements before the products enter the marketplace. The Department is the only state agency with comprehensive expertise, experience and training in the dairy industry from farm to table, including milk pasteurization technology and laboratory issues, unique to the dairy industry.

The Milk and Dairy Food Safety Branch also provides training and supervision for local Approved Milk Inspection Services to develop statewide uniformity. Dairy Foods Specialists inspect dairy farms and milk processing plants, and collect samples of milk and milk products to ensure consumer safety as well as check fail-safe systems on pasteurization equipment, and evaluate dairy farms, milk plants, and laboratories for the United States Food and Drug Administration (FDA) for the safety of dairy products in interstate commerce.

On October 24, 2002, the Dairy Institute of California petitioned the Department to initiate a rulemaking action to establish testing procedures that must be followed in determining whether California fluid milk products comply with the compositional standards imposed by sections 35784, 38181, 38191 and 38211 of the Food and Agricultural Code for each respective product.

Pursuant to Government Code section 11340.7, the Department issued its decision to the petitioner, dated November 22, 2002, and properly noticed its decision in the December 13, 2002 edition of the *California Regulatory Notice Register*. The Department acknowledged that current regulations need to reflect the laboratory procedures and analytical methods used to obtain the compositional fat, solids not fat, and total solids content of finished fluid milk products referenced in Food and Agricultural Code sections 35784, 38181, 38191 and 38211.

On April 7, 2006, the Department met with representatives of the Dairy Institute of California regarding regulations for fluid milk composition testing. Subsequently, on April 27, 2006, the Dairy Institute of California withdrew its petition for rulemaking, “. . . if the Department intends to initiate rulemaking aimed at developing regulations on the same topics as authorized by sections 32921 and 34261.5 of the Food and Agricultural Code.”

Therefore, the Department is establishing criteria for approval of infrared (IR) instruments to be used for fluid milk composition analysis. This regulation will make California consistent with United States Department of Agriculture (USDA) practices to ensure the Department's producer payment program is using the most advanced analytical technology for milk composition analysis. Further, current industry practice and federal law allow for more current methodologies and technologies that are more accurate and precise than those cited in Food and Agricultural Code section 32921 for determination of components of milk and milk products to meet compositional requirements at the time of delivery to the consumer. The Department may adopt, by regulation, other acceptable methods of comparable accuracy to become current with available technology and consistent with federal law.

Additionally, also included in this proposal are updated procedures and requirements for the application and examination of persons applying for licensure as a pasteurizer operator, tester, butter grader, sampler and weigher, and technician. This proposal specifies the application forms, incorporated by reference, that are required by the Department, and updates Department and industry terminology where appropriate.

Listed below is the justification and rationale for each proposed adoption, amendment, and repeal of specified sections under Chapter 1, Division 2, of Title 3, of the California Code of Regulations.

### **Amend Article 13. Personal Licenses and Examinations**

The Department is amending the heading of Article 13 for consistency throughout this article to designate the required "personal examinations and licenses" as an examination must be successfully completed by the applicant prior to licensure. Milk and dairy products undergo a number of safety, quality, and sanitation procedures making them among the most highly regulated and safest foods available to consumers. To ensure the safety and quality of milk and milk products, and the accuracy of sample collection and raw milk analysis for fair producer payment, the Department administers examinations for the licensure of operators of pasteurizing equipment, testers to test components of milk or cream, butter graders to assess butter for quality, samplers and weighers to collect representative samples of raw milk from farm tanks and bulk milk tankers, and technicians to make bacteriological determinations of milk or cream working in the dairy industry. The sections under Article 13 are as follows:

#### **Amend Section 498. Pasteurizer Examination.**

The Department is amending the heading to clarify that the section pertains to the pasteurizer's examination and the pasteurizer's license.

Subsections (a) and (a)(1) are added to clarify the requirements for initial license application, the form required, and that the fee submitted is nonrefundable.

Subsection (a)(2) is added and reorganized to update the examination requirements for licensure. The Department is adding the requirement for a passing grade of at least 80 percent on the written examination, and a grade of at least 80 percent on an oral and practical examination. Pasteurizing equipment is complex, and is designed to ensure that raw milk is heated in properly constructed and operated equipment according to specific time and temperature requirements to ensure milk safety. The examination requirements are in place to ensure the applicant can demonstrate their knowledge and skills required to operate the pasteurizing equipment.

Subsection (b) is added to require each licensed pasteurizer to keep their license displayed at all times where they are employed. This requirement will ensure the person employed is properly trained and licensed by the Department pursuant to Food and Agricultural Code section 35168.

#### **Amend Section 499. Milk and Cream Tester's Examination.**

The Department is amending the heading to specify tester's examination and license, eliminating the phrase "Milk and Cream" for consistency with Food and Agricultural Code section 35161 which specifies a "Tester's License".

Subsections (a) and (a)(1) are added to clarify the requirements for initial license application, the form required, and that the fee submitted is nonrefundable.

Subsection (a)(2) is added and reorganized to update the examination requirements for licensure. The Department is adding the requirement for a passing grade of at least 80 percent on the written examination, and a grade of at least 80 percent on an oral and practical examination. The testing of milk and cream is complex, and the examination requirements are in place to ensure the applicant can demonstrate their knowledge and skills required to operate the equipment.

Subsection (b) is amended to specify the types of testing methods acceptable to the Department. This section also specifies that a tester may be licensed to perform each of the methods described in section 32921 of the Food and Agricultural Code and section 511 of this proposal.

Subsection (c) is needed to clarify that a licensed tester must comply with all laws, rules and regulations for the testing of milk or cream purchased, received, or sold on the basis of the components of milk contained by any method or process, and must secure accurate results. Milk testing methodology must be followed precisely in order for laboratory analyses and reporting of results to be accurate. These results impact billions of dollars in payment to milk producers as well as trigger regulatory enforcement activities by the Department.

Subsection (d) is added to require each licensed tester shall keep their license displayed at all times where they are employed. This requirement will ensure the person employed is properly trained and licensed by the Department pursuant to Food and Agricultural Code section 35170.

#### Repeal Section 499.5. Nonfat Milk Solids Tester's License.

The Department is repealing this section because nonfat milk solids are automatically or mathematically quantified with other test methods conducted by licensed Testers. This eliminates the need for a separate license category for a nonfat milk solids tester's license.

#### Adopt Section 499.5. Butter Grader's Examination and License.

The Department is relocating text from former section 508 so that all personal licensed appear in consecutive order.

Subsections (a) and (a)(1) are added to clarify the requirements for initial license application, the form required, and that the fee submitted is nonrefundable.

Subsection (a)(2) is added and reorganized to update the examination requirements for licensure for persons who certify the score or grade of butter. The Department is adding the requirement for a passing grade of at least 80 percent on the written examination, and a grade of at least 80 percent on an oral and practical examination. The examination requirements are in place to ensure the applicant can demonstrate their knowledge and skills required to properly grade butter.

Subsection (b) is added to require each licensee to keep their license displayed at all times where they are employed. This requirement will ensure the person employed is properly trained and licensed by the Department pursuant to Food and Agricultural Code section 35134.

Amend Section 500. Sampler's and Weigher's Examination.

The Department is amending the heading to specify a sampler's and weigher's examination and license for consistency throughout Article 13. Samples of bulk tank milk are collected regularly and milk quality tests are performed, and the Department issues licenses to persons who qualify for sampling and weighing raw milk.

Subsection (a) is added to clarify that there are two types of licenses issued by the Department, which are a general and limited license for sampler's and weigher's pursuant to Food and Agricultural Code section 35163, and California Code of Regulations section 576.1(c) which derives authority from Food and Agricultural Code section 32761.5.

Subsection (b) includes the statute and regulation citations for persons that must obtain a sampler's and weigher's license.

Subsection (b)(1) is added to clarify the requirements for initial application, the form required, and that the fee submitted is nonrefundable.

Subsection (b)(2) updates the requirements for examination and that a passing grade of at least 80 percent is required on the written examination, and must be specific to the type of license that the Department issues.

Subsection (b)(3) updates the requirements for the oral and practical examination for a general sampler and weigher license, that a passing grade of at least 80 percent must be obtained by the applicant. The examination requirements are in place to ensure the applicant can demonstrate their knowledge and skills required to properly sample and weigh milk.

Subsection (b)(4) updates the requirements for the oral and practical examination for a limited sampler and weigher license, that a passing grade of at least 80 percent must be obtained by the applicant. The examination requirements are in place to ensure the applicant can demonstrate their knowledge and skills required to properly sample and weigh milk.

Subsection (c) is added to require each general sampler and weigher licensee to keep their license on their person and available for inspection at all times during their work as a licensee. This requirement will ensure the person employed is properly trained and licensed by the Department pursuant to Food and Agricultural Code section 35163 and 35171.

Subsection (d) is added to require each limited sampler and weigher licensee to keep their license displayed at all times where they are employed. This requirement will ensure the person employed is properly trained and licensed by the Department pursuant to Food and Agricultural Code section 35171, and California Code of Regulations section 576.1(c).

Amend Section 501. Technician Examination.

The Department is amending the heading to clarify that this section pertains to the technician's examination and "license". Every person who makes any bacteriological determination of milk or cream which is to be used as a basis of payment or determining value must be licensed by the Department.

Subsections (a) and (a)(1) are added to clarify the requirements for initial license application, the form required, and that the fee submitted is nonrefundable.

Subsection (a)(2) is added and reorganized to update the examination requirements for licensure. The Department is adding the requirement for a passing grade of at least 80 percent on the written examination, and a grade of at least 80 percent on an oral and practical examination. The examination requirements are in place to ensure the applicant can demonstrate their knowledge and skills required for a technician's license.

Subsection (b) is added to require each licensee to keep their license displayed at all times where they are employed. This requirement will ensure the person employed is properly trained and licensed by the Department pursuant to Food and Agricultural Code section 35167.

Amend Section 502. Standard Methods for Examination of Dairy Products.

The Department is deleting inaccurate text, as section 35167 does not require sample collection under the supervision of a licensed technician. The Department is also specifying the correct edition of the "Standard Methods for the Examination of Dairy Products" to be followed for sample collection protocol.

Repeal Section 503. Duplicate Records.

The Department is repealing this section because currently applicable text from this section is being combined into section 504; and removing references to pencil and carbon paper to allow for other duplication methods.

Amend Section 504. Form for Bacteria Count.

The Department is amending the heading to use current laboratory terminology, which is "bacteriological record sheets".

Subsection (a) is amended to eliminate the Departmental approval requirement because it is no longer necessary.

Subsections (b), (c), and (d) clarify the handling of original and duplicate record sheets. The Department determined that a need exists to provide details for industry

to comply with the requirements of this section. The Department believes that the 30-day minimum for the availability of duplicate records is adequate, taking into consideration that the majority of dairy products are perishable and would be consumed within 30 days, and then the records may be archived and stored by the laboratory. The requirement for records storage for a minimum of two years would allow for retrieval of records for a period within which even dry or sterile dairy products are likely to have been consumed.

The term "concern" used in subsections (b) and (c) above is a common term that is used and understood in the dairy industry to indicate an individual producer, a handler organization or a processing plant.

Amend Section 505. Changing Records.

The Department is updating this section by eliminating references to pencil, and to a sealed box for sample sheets, as these requirements are no longer necessary.

Repeal Section 506. Bacteriological Record Sheets.

The Department is repealing this section because currently applicable text from this section is being combined into section 504; and an official record box is no longer required so this text is repealed.

Repeal Section 508. Butter Grader's License.

The Department is repealing this section and moving the text to new section 499.5 so all personal licenses appear consecutively in the beginning of Article 13.

**Amend Article 14. Official and Approved Testing Methods**

The Department is amending the heading to clarify that "protocols" are covered as well as testing methods. The United States Department of Agriculture (USDA), Market Administrator's office, has accepted criteria for infrared instrumentation and protocols to be used for the most equitable payment to dairy producers for their milk. The Association of Official Analytical Chemists, International (AOAC), which establishes requirements for the accuracy of milk and dairy product analyses, has accepted the same instrumentation and methodology. Laboratory methods using this instrumentation are cited in Standard Methods for the Examination of Milk and Milk Products, 17<sup>th</sup> Edition, published by the American Public Health Association (APHA), 1015 Fifteenth Street, NW, Washington, DC 20005, and in Official Methods of Analysis, 18<sup>th</sup> Edition, published by AOAC, 481 N. Frederick Avenue, Suite 500, Gaithersburg, MD 20877, Therefore, the Department is incorporating by reference the Official Methods of Analysis of the Association of Official Analytical Chemists International and the Standard Methods for Examination of Milk and Milk Products, as specified.

Current text in this article addresses raw milk for producer payment. The Department determined that a need exists to also address testing methods and protocols for bulk milk, finished milk products and products resembling milk products, and has made amendments to include testing methods for these products. The sections under Article 14 are as follows:

Amend Section 509. Official and Approved Testing Methods.

The Department making grammatical corrections for consistency purposes, and is amended to clarify the dairy products governed by Article 14.

Amend Section 510. Official Final Action Methods of Analysis.

The Department is making technical revisions by changing "director" to "Department" and to specify the correct version, date and title for the 18<sup>th</sup> Edition of the Official Methods of Analysis of the Association of Official Analytical Chemists International (AOAC). AOAC is a 120 year-old not-for-profit scientific association committed to worldwide confidence in analytical results, which provides input on the development of international standards for foods and agriculture. AOAC Official Methods of Analysis have been defined as "official" by regulations promulgated for enforcement of the Food, Drug, and Cosmetic Act (21 CFR), recognized in 9 CFR of the USDA, Food Safety and Inspection Service regulations, and in some cases by the US Environmental Protection Agency.

Amend Section 511. Approved Testing Methods of Comparable Accuracy.

The Department is making amendments to subsections (a) and (a)(1) through (15) to clarify the dairy products governed by this section, and is making technical revisions to specifically identify the currently acceptable laboratory methodologies of comparable accuracy for various components. Amended text includes testing methods for bulk milk and finished products, in addition to those for basis of payment, consistent with Food and Agricultural Code section 32921. Text limiting methods only to producer payment is repealed.

Subsection (b) makes a technical revision to section number of a referenced chart.

Amend Section 512. Testing Procedures and Equipment.

The Department is making a technical revision by changing "director" to "Department", and to specify the correct version and title for the 18<sup>th</sup> Edition of the Official Methods of Analysis of the Association of Official Analytical Chemists International.

Subsection (b) is added to clarify procedures for laboratories that test raw milk for producer payment using infrared instrumentation, and for approval of those instruments. The subsequent subsection reference is changed to (c).

Amend Section 512.1. Testing Equipment.

The Department is making technical revisions by changing "director" to "Department", and to specify the current version and title for the 18<sup>th</sup> Edition of the Official Methods of Analysis of the Association of Official Analytical Chemists International. The Department is also updating the requirements for the standards for laboratory glassware and eliminates the Departmental examination requirement because it is no longer necessary.



Amend Section 512.2. Character of Work and Tolerances.

The Department is making the following amendments to specify currently required parameters for milk component testing.

Subsection (a) includes a technical revision to reference the "Department" for consistency throughout the regulations.

Subsection (b) expands Departmental notice of obtaining industry samples to allow other than written notice to expedite communication regarding perishable samples, and provides options of either having a sample collected and transported to the Department's dairy chemistry laboratory or having a Tester retest a sample on site.

Subsection (c) makes grammatical and subsection reference changes.

Subsection (d) deletes the table, which is replaced with an updated table in subsection e, and clarifies that the Department will provide calibration samples for infrared instrumentation used for basis for payment analyses, incorporates applicable text from repealed section 553(f), and specifies that those laboratories must meet precision and accuracy requirements.

Former subsection (e) is repealed and eliminates the unnecessary examples 1 and 2 of laboratory results that do not meet precision and accuracy requirements, respectively.

Subsection (e) renumbers and updates the table in former subsection (d) (by replacing the entire table rather than presenting it in combined strikeout and underline format) that specifies accuracy and precision requirements for persons making milk component tests by approved methods for payment purposes.

Subsection (f) clarifies conditions for a milk sample retest result to be reported or for averaging of prior test results.

Subsection (g) is added to clarify conditions for reporting an original test result over a retest result.

Former subsection (g) makes a subsection reference change to (h) and clarifies conditions for a cream sample retest result to be reported or for averaging of prior test results.

Former subsection (h) makes a subsection reference change to (i) and specifies that unannounced inspections may be conducted to check a licensed tester's work and that the Department will review a tester's work when a complaint is received.

Former subsection (i) is repealed, and eliminates obsolete text regarding inactive and relief testers.

Repeal Section 512.3. Licensing.

The Department is repealing text duplicative of section 499.

Adopt Section 513. Infrared Instrumentation.

This section, formerly titled “Babcock, Gerber and Mojonnier Tests,” was repealed effective January 1, 1980. This location is appropriate to add text regarding infrared instrumentation, so the Department is adding this section with the heading “Infrared Instrumentation” to adopt current mid-infrared instrumentation for use on basis for payment samples and on compliance samples.

Adopt Section 513.5. Operation of Infrared Instruments.

This section is added to clarify the conditions under which infrared (IR) instruments shall be operated for milk component testing. The requirements under this section are necessary to ensure IR instrumentation is properly performed by licensees. As stated previously, milk testing methodology must be followed precisely in order for laboratory analyses and reporting of results to be accurate. These results impact billions of dollars in payment to milk producers as well as trigger regulatory enforcement activities by the Department. Applicable text from repealed section 547 is incorporated in this section.

Subsection (a)(1) clarifies that persons operating IR instruments for basis for payment purposes, and their supervisors, shall hold Tester’s licenses.

Subsection (a)(2) specifies protocol for the pilot sample and its use throughout the day as a check on the IR instrument’s proper calibration or malfunction, and laboratory actions to be taken in the event of IR instrument malfunction. This subsection also specifies when pilot sample results would trigger averaging of payment sample results and specifies requirements for the laboratory management to submit a letter to the Department identifying the alternate official final action methods and/or alternate laboratory that shall be used to analyze payment samples in the event of instrument malfunction, and to update the letter as circumstances change.

Subsection (a)(3) specifies that raw milk samples in poor condition shall not be tested by IR. Raw milk that is high in acidity, coagulated or churned will clog the IR instrument and cause repairs to be necessary, as well as provide unacceptable milk sample results on this instrument.

Subsection (a)(4) specifies laboratory actions to be taken in the event the licensed Tester has reason to believe the IR results are biased or inaccurate.

Subsection (a)(5) specifies that the IR instrument manufacturer’s instruction manual shall be followed in regard to calibration, preparation, maintenance and cleaning. This subsection also specifies that a log book shall be maintained, posting all pilot sample results and instrument adjustments, and shall be available for review by the Department upon request.

Subsection (a)(6) specifies that the volume of sample to be tested shall be sufficient to make an original test and a re-test.

Subsection (a)(7) specifies that a constant voltage regulator shall standardize the power supply to the IR instrument.

Subsection (a)(8) specifies that temperature in the room where the IR instrument is operated shall not exceed 80°F.

#### Amend Section 514. Samples, Sampling and Weighing.

This section is reorganized to clarify the protocol for mixing of bulk samples, eliminates text inconsistent with current protocol on mixing, technical revision in reference to the Department, eliminates obsolete text and subsection on composite samples, re-numbers subsequent sub-sections, specifies information required on samples and removes irrelevant reference to re-issuance of patron numbers, a grammatical correction regarding responsibility of licensees (licensees are responsible for agitation of bulk products from which a sample is to be taken, but not for the proper operation of the agitators themselves which is the responsibility of the dairy farm owner), and eliminates text on displaying tester's licenses which is duplicative of section 499.

#### Amend Section 515. Cream Sample Bottles.

The Department is amending the heading to clarify that this section pertains to sample bottles. The reference to "cream" sample bottles is eliminated because current sample containers are uniform regardless of the sample being milk or cream. Also, this section specifies the requirements for the sample bottles to eliminate Departmental approval for same. The added requirements clarify that industry persons are to ensure that all milk and cream sample bottles are made from plastics that do not contain any chemicals that could adversely affect the composition or bacteriological quality of the product.

#### Amend Section 516. Milk Preservatives.

This section is amended to specify the compounds, and the respective concentrations, that are approved for preserving milk samples to be tested as basis for producer payment. Former text regarding time composite samples has been deleted, as this practice is obsolete and no longer done.

#### Amend Section 517. Storage and Testing of Samples.

This section is amended to update laboratory protocols for handling of milk samples that are tested as basis for producer payment.

Subsection (a) is added to specify that laboratories approved for basis for payment testing designate a licensed Tester (designee) to be responsible for oversight of proper sample receipt, storage, handling, preparation, testing, and recording of analytical results. Relevant CCR sections are specified to include those issues addressed that relate to sample receipt, storage, handling, preparation, testing, and recording of analytical results. This subsection further specifies that the designee

will ensure all personnel who test samples for payment are licensed Testers, and will have oversight of proper infrared (IR) instrumentation calibration and maintenance. This subsection also specifies that laboratories approved for basis for payment testing shall notify the Department within 24 hours should the designee change, and that the laboratory shall have a trained backup designee available.

Subsection (b) is renumbered from former subsection (a) and has technical revisions to specify current terminology and refrigerator requirements for milk samples. References to a locked area for sample storage are obsolete and were deleted. This subsection is amended to specify that written laboratory protocols regarding security of laboratory samples are required and shall be submitted to the Department at the time the laboratory requests approval to test milk samples for the basis for payment program.

Former subsection (b) is deleted, as 4-day accumulation and compositing of milk samples is obsolete. Current farm milk volumes require a minimum of once daily collection at the dairy farm, and current industry practices ensure milk samples are analyzed within 3 days of collection. The reference to Food and Agricultural Code section 34231(f) was duplicative of text in that statute and unnecessary.

Subsection (c) has technical revisions to specify that the payment laboratory and not the licensed Tester will retain milk samples for 72 hours after testing in case a re-test is required. Text on time composites is obsolete and is deleted.

#### Amend Section 525. Keeping Records of Tests.

This section is amended to address current laboratory record-keeping protocol.

Former subsection (a) is deleted. The Department is removing references to pencil and carbon paper to allow for other duplication methods.

Subsection (a) specifies that test record sheets be identified with the name and address of the concern for which the tests are made, and clarifies the handling of test record sheets and duplicates. The Department determined that a need exists to provide details for industry to comply with the requirements of this section. The Department believes that the 30-day minimum for the availability of daily test records is adequate, taking into consideration that raw milk is perishable and would be processed and consumed within 30 days. The requirement for records storage for a minimum of two years would allow for retrieval of records for a time period reflecting common industry practices.

Former subsection (b) is deleted entirely, to eliminate the Departmental approval requirement because it is no longer necessary.

Subsection (c) makes a subsection reference change to (b) and amended to specify requirements that the name and address of the testing laboratory and serial number of Infrared instruments used appear on test record sheets.

Subsection (d) makes a subsection reference change to (c) and amended to specify test results to be considered “sufficiently different” by referencing the precision and accuracy chart in CCR section 512.2(e), and has technical revisions to eliminate reference to use of a pencil. A sealed box, and specific dimensions of record sheets are no longer required so this text is repealed.

Subsection (e) is repealed, as its text conflicts with requirements in table 512.2 e. Amending the text here would be duplicative of text in section 512.2(f) and 512.2(g).

Subsection (f) makes a subsection reference change to (d).

Subsection (g) is repealed, as a sealed box is no longer required.

Subsection (h) makes a subsection reference change to (e).

Subsection (i) makes a subsection reference change to (f) and includes a technical revision by changing “director” to “Department”.

Subsection (j) makes a subsection reference change to (g) and clarifies that explanations as to averaged tests on milk, the amount of fat or cream, and averages in weights or measurements must appear only on the original patron statement.

Repeal Section 527. Observation of Laws, Rules and Regulations.

The Department is eliminating text duplicative of section 499.

**Repeal Article 14.5. Nonfat Milk Solids Testing and Reporting**

Nonfat milk solids are not directly determined by laboratory test methods, they are mathematically calculated by subtraction of the milk fat determined by one test method from the total milk solids value from another. In the case of infrared (IR) testing the nonfat milk solids are mathematically predicted based on the absorbance of infrared light by fat, protein and lactose, and reported along with several other milk components. Test methods for milk fat, and total milk solids, and IR component determinations each have respective laboratory protocols to follow. Therefore, text regarding nonfat milk solids testing and sample handling practices is unnecessary. Listed below are the sections repealed under Article 14.5.

Repeal Sections 536 (Operations and Methods), 537 (Samples and Records), 538 (Preserving and Compositing of Samples), 539 (Test Room Equipment for Nonfat Milk Solids Testing), 540 (Averaging of Tests) and 541 (Samples).

The Department is repealing these sections because nonfat milk solids mathematically quantified with current test methodologies. Therefore separate text regarding testing and sample handling practices for nonfat milk solids testing is repealed.

### **Repeal Article 14.6. Testing of Raw Milk for Butterfat by Light Transmission**

This test method and its instrumentation were developed in the early 1970s and the Milko-Tester is no longer being manufactured. Advancement of more accurate and effective milk fat test methodologies and instrumentation since then has made this milk fat test method unacceptable to the Department and not comparable to test methods currently available. Listed below are the sections repealed under Article 14.6.

#### **Repeal Sections 543 (Milko-Tester) and 544 (Milko-Tester Operation).**

The Department is repealing these sections because the Milko-tester instrument is no longer being produced for sale or used in basis for payment laboratories. Advancements in laboratory testing and technology since the 1970s have made this instrument obsolete. Therefore text regarding this test method and instrument is repealed. This instrument, even if it did still exist, would not be able to meet current precision, accuracy, and pilot sample reproducibility parameters as outlined in Section 512.2 (e) and Section 513.5.

### **Repeal Article 14.7. Testing of Raw Milk for Butterfat and Other Milk Constituents by Infrared Light Transmission**

This test method and its instrumentation were also developed in the early 1970s. Advancement of technology for multiple milk component testing has created additional, and more accurate and effective instrumentation for this purpose. Text regarding currently acceptable infrared (IR) methodology is added in sections 513 and 513.5 and is placed there to be immediately after sections describing precision and accuracy requirements within Article 14, which describes official and approved testing methods and protocols. Text from this Article that is still pertinent has been moved to sections 513 and 513.5. Listed below are the sections repealed under Article 14.7.

#### **Repeal Sections 546 (Infrared Milk Analyzer (IRMA)) and 547 (Operation of IRMA).**

The IRMA brand infrared analyzer instrument is one of many brands of instruments acceptable for official testing of milk, and is now obsolete. Therefore text regarding this specific brand of instrument is repealed, and applicable portions of text from this section have been incorporated into sections 513 and 513.5 in generic terms.

### **Article 14.8. Third Party Testing**

The Food and Agricultural Code section 34231 specifies that determination of milk fat and fluid skim milk components shall be made through tests performed in facilities approved by the director, and that the director shall, as one of several options, designate independent testing facilities to perform tests for producer payment in the absence of mutual agreement between parties affected. The independent testing facilities conduct third party testing for producer payment. Food and Agricultural Code section 34231, further, states that costs for such tests are to be borne equally between the producer and distributor except in the case of interplant sales or delivery from nonprofit cooperatives to a distributor. The sections under Article 14.8 are as follows:

Repeal Section 550. Purpose.

The Department is repealing this section for lack of necessity and it duplicates the authority and reference citations of the sections under this article.

Amend Section 551. Definitions.

The Department is making a minor technical revision by changing "director" to "Department" for consistency and clarity purposes.

Amend Section 552. Interpretation of Section 34231(e).

The Department is amending the heading to clarify that this section pertains to "interplant bulk sales of commingled milk".

Subsection (a) is repealed for lack of necessity and it duplicates the authority and reference citations of the sections under this article.

Subsection (b) makes a subsection reference change to (a) and a technical revision to use lower case type in "section".

Subsection (c) makes a subsection reference change to (b), makes a technical revision to use lower case type in "section" and makes grammatical corrections to clearly indicate that this subsection pertains to individual producers.

Amend Section 553. Procedures for Assignment.

The Department is amending the heading to "Procedures for Designation" for consistency with text in Food and Agricultural Code section 34231. The preamble and subsections are revised to reflect current test methods and industry practices.

Subsection (a) is repealed, as the Department has never been requested to provide state employees to test basis for payment samples. The option to designate independent testing facilities to perform basis for payment tests, allowed in Food and Agricultural Code section 34231, has become the industry standard. State employees do not perform basis for payment tests in industry facilities, making this subsection unnecessary.

Subsection (b) and (b)(1) through (3) are repealed. The option to designate independent testing facilities to perform basis for payment tests, allowed in Food and Agricultural Code section 34231, has become the industry standard, so county health department laboratories do not perform basis for payment tests, making this subsection unnecessary.

Subsection (c) is repealed, as geographical areas no longer need to be considered with the availability of statewide overnight shipment of milk samples, making this subsection unnecessary.

Subsection (d) and (d)(1) through (4) make a subsection reference changes to (a) and (a)(1) through (3) and amends the text to eliminate unnecessary references to geographic area.

Former subsection (d)(3) is repealed to eliminate unnecessary text regarding logistical requirements, and former section (d)(4) makes a subsection reference change to (a)(3).

Subsection (e) is repealed to eliminate unnecessary text regarding geographical area, and text regarding test methods, which, if amended to reflect currently approved tests, would have been duplicative of that in section 511.

Subsection (f) is repealed, and its text regarding calibration samples is added in sections 512.2 (d) and is placed there consistent with text regarding precision and accuracy requirements for laboratories performing basis for payment tests.

Subsection (g) is repealed to eliminate unnecessary text. Food and Agricultural Code section 34231 allows for the Department to be involved in contracts with the Department or with an approved milk inspection service, but not between industry parties.

Subsection (h) makes a subsection reference change to (b) and makes technical revisions from “assignment” to “designation” for consistency with text in Food and Agricultural Code section 34231.

Subsection (i) is repealed. The Department does not provide basis for payment tests under contract, making this subsection unnecessary.

Subsection (j) makes a subsection reference change to (c), and makes technical revisions by changing to lower case type in “section”, by specifying that the referenced section 34231(c) is from the Food and Agricultural Code, by changing “director” to “Department”, and by changing “assignment” to “designation” for consistency with text in Food and Agricultural Code section 34231.

#### Amend Section 554. Resolution of Test Variations.

The Department is making minor technical revisions to this section to specify that section 34231 is from the Food and Agricultural Code, and makes a grammatical correction.

### **Article 21. Milk Inspection Services**

The Department is amending one section in this article that pertains to milk composition test results, and required confirmation and reporting of test results prior to enforcement action being taken for failure to meet milk composition standards. The amended section under Article 21 is as follows:

#### Amend Section 604.1. Analysis Confirmation.

The Department is amending the heading to “Confirmation of Compliance Testing on Finished Fluid Milk Products” and deleting this section to replace it with updated requirements. The reference to Approved milk Inspection Service is deleted as the Department has jurisdiction over all processing of milk products statewide.



Subsection (a) is added to clarify that testing of finished fluid milk products by infrared analysis shall be confirmed by other specified testing methods, based on the respective milk component(s), prior to enforcement action being taken.

Subsection (a)(1) specifies the confirmation test method to be used for milk fat.

Subsection (a)(2) specifies the confirmation test method to be used for total milk solids.

Subsection (a)(3) specifies the confirmation test method to be used for solids not fat in milk.

Subsection (b) is added to clarify that finished fluid milk test results shall have an expanded uncertainty value taken into consideration, when compliance with legal standards for milk composition is being determined. Expanded uncertainty provides an interval within which the value of the measurand is believed to lie, with a high level of confidence. Uncertainty of measurement does not imply doubt about the validity of a measurement; on the contrary, knowledge of the uncertainty implies increased confidence in the validity of a measurement result.

Subsection (b)(1) specifies the expanded uncertainty to be applied to milk fat test results on milk, reduced fat milk, lowfat milk and nonfat milk.

Subsection (b)(2) specifies the expanded uncertainty to be applied to total milk solids test results on milk. There is not a standard for total milk solids on reduced fat milk, lowfat milk or nonfat milk.

Subsection (b)(3) specifies the expanded uncertainty to be applied to solids not fat test results on milk, reduced fat milk, lowfat milk and nonfat milk.

Text following subsection (b)(3) defines expanded uncertainty.

Subsection (c) provides a mechanism for industry persons to submit complaints regarding test results. The Department will maintain a file of the written complaints for two years.

### **Underlying Data**

1. Petition from the Dairy Institute of California dated October 24, 2002
2. Department's response to petition dated November 22, 2002
3. STD. 400/publication of the Notice of Decision on Petition for Rulemaking
4. Meeting agenda dated April 7, 2006, with the Dairy Institute of California
5. Minutes of the April 7, 2006 meeting (w/attach) with the Dairy Institute of California
6. Letter from Knox, Lemmon, Anapolsky, LLP, dated April 27, 2006

The following publications and forms specified in this proposal are incorporated by reference because the documents are specific to the dairy industry, and the publications are voluminous and not practical for inclusion in this filing. The general public is not directly regulated by this proposal, however, they benefit from the standards and requirements established by the Department for the safety of dairy products and the inspection and testing activities of the Department and the dairy industry. Industry persons are provided with the appropriate forms and publications, and/or are provided with information on how to obtain specific sections of the referenced documentation.

7. Standard Methods for the Examination of Dairy Products (SMEDP), 17th Edition, published by the American Public Health Association: Information.
8. Official Methods of Analysis, 18<sup>th</sup> Edition, published by the Association of Official Analytical Chemists International (AOAC): Information; Methods [per sections 511 and 604.1 of this proposal]; Measuring Glassware.
9. Pasteurizer's License Application, Form No. 72-255 (Rev. 7/05)
10. Tester's License Application, Form No. 72-202 (Rev. 11/05)
11. Butter Grader's License Application, Form No. 72-267 (Est. 7/05)
12. Sampler's and Weigher's License Application, Form No. 72-246 (Rev. 2/06)
13. Technician's License Application, Form No. 72-252 (Rev. 7/05)

### **Business Impact**

The Department has made an initial determination that the proposed regulatory action would have no significant statewide adverse economic impact directly affecting California businesses, including the ability of California businesses to compete with businesses in other states. The following compliance requirements are projected to result from the proposed action:

(1) Paperwork: Application forms are required for persons applying for licensure as a pasteurizer operator, tester, sampler and weigher, or technician. A detailed list, including the form numbers, is included in the rulemaking file. Application fees are assessed pursuant to Food and Agricultural Code 35231.

(2) Reports and records: Licensed technicians are required to maintain Bacteriological Record Sheets and laboratories are required to maintain Milk and Cream Test Records. Record keeping is a standard business practice and therefore the Department does not believe this existing requirement will impose any adverse economic impact upon businesses.

### **Specific Technologies or Equipment**

This regulation does mandate the use of specific technologies or equipment. However, the Department may, by regulation, adopt acceptable technologies or equipment consistent with the United States Department of Agriculture and the national standards for the dairy industry to test fluid milk composition.

### **Consideration of Alternatives**

No reasonable alternative which was considered or that has otherwise been identified and brought to the attention of the Department would either be more effective in carrying out the purpose for which the action is proposed or would be as effective as and less burdensome to affected private persons than the proposed regulation.